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PERELIZZI

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
		HM3170622	
ENZO DIAGNOSTICS, INC. C/O ENZO BIOCHEM, INC. 527 MADISON AVENUE (9TH FLOOR) NEW YORK NY 10022			MARSCHEL, A
		1694	EXAMINER
		06/22/98	ART UNIT
			PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>07/479,995</b>	Applicant(s) <b>Pergolizzi et al.</b>
	Examiner <b>Marschel, Ardin</b>	Group Art Unit <b>1634</b>

Responsive to communication(s) filed on 3/25/98 and 3/30/98

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 283-362, 364-380, 382-398, 400-404, 406-439, and 441-463 is/are pending in the application.

~~Of the above, Claim(s) 1-282, 363, 381, 399, 405, and 440 have been canceled.~~

Claim(s) 364-380, 382-398, 400-404, 406-410, 412, 415, 417, 439, and 442-463 are allowed.

Claim(s) 283-296, 298-301, 304, 307, 309-321, 323-333, 335-340, 347, 350, 353, 358-362, 411, 413, 414, 416, 418, 419, 422-425, 432, 433, 436-438 are rejected.

Claim(s) 297, 302, 303, 305, 306, 308, 322, 334, 341-346, 348, 349, 351, 352, 354-357, 420, 421, 426-431, 434, and 435 are objected.

Claims 354-357, 420, 421, 426-431, 434, and 435 are objected. are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed.

Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1634.

Applicants' arguments and Declaration, filed 3/25/98 and 3/30/98, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claims 312, 318, and 330 are rejected, as discussed below, under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

This rejection is maintained and reiterated from the previous office action, mailed 10/27/97, as it was not responded to in the response, filed 3/25/98. Claims 312, 318, and 330 cite all options for modifications and thus fail to further limit the claims from which they depend.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 283-296, 298-301, 304, 307, 309-321, 323-333, 335-340, 347, 350, 353, 358-362, 411, 413, 414, 416, 418, 419, 422-425, 432, 433, 436-438, 441, and 461-463 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Dunn et al.

This rejection is maintained and reiterated from the previous office action, mailed 10/27/97, only regarding the instant composition claims and necessitated by amendment regarding the newly added claims. This will be discussed below. Firstly, the withdrawl of the instant detection method claims from this rejection is based on the persuasive arguments of applicants and the Declaration of Dr. Wetmur as to what is characterized as the analyte or target in the method of Dunn et al. or sandwich hybridization assays such as that of Ranki et al. (P/N 4,486,539). For example, in instant claim 442 the analyte detection conclusion is drawn from the signal produced by the signalling entity. This analyte is not hybridized between two polynucleotide probes but rather only specifically hybridized to the bridging polynucleotide which is turn is specifically hybridized to the signalling polynucleotide at another segment within the bridging entity. In such methods the entity referred to as the analyte or target is related to the signal and therefore its location within the sandwich is critical. Turning back to the composition claims, the analysis is not the same. Composition claim subject matter is exactly that. It is a composition. In the instant claim 283, for example, two polynucleotides are claimed with certain hybridization

characteristics. Three entities are described so as to define these hybridization characteristics. These are the analyte, molecular bridging entity, and the signalling entity(ies). When the composition is, however, viewed as to what it actually is, it is at least two polynucleotides with specific hybridization capabilities to other specific polynucleotides. Such specificity of hybridization to certain polynucleotides is also a characteristic of polynucleotides of Dunn et al. The naming of these polynucleotides as analyte, bridging, and signalling entities cannot convey patentable distinctness over polynucleotides with the same specificity characteristics such as given in Dunn et al., although naming the polynucleotides differently. If naming entities alone within composition claims conveyed patentable distinctness, while acknowledging that sequence specificity and any other characteristics, for example, are the same, then naming the polynucleotides of such a composition with novel names would result in patentability. Clearly, this would be unreasonable and generate undue confusion because novel names can be generated at will if desired. In summary, the instant composition claims, kit claims, and articles of manufacture citing the same compositions are still deemed properly rejected hereinunder.

Claims 297, 302, 303, 305, 306, 308, 322, 334, 341-346, 348, 349, 351, 352, 354-357, 420, 421, 426-431, 434, and 435 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all

of the limitations of the base claim and any intervening claims.

Claims 364-380, 382-398, 400-404, 406-410, 412, 415, 417, 439, and 442-460 are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee for a large entity under 37 CFR 1.17(r), the finality of the

previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

June 19, 1998

*Ardin H. Marschel*  
ARDIN H. MARSHEL  
PRIMARY EXAMINER